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EXAMINER	
PORTER, RACHEL L	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/710,227	GOURLEY, EWING B.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004 and 12 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49 and 62-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49 and 62-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the amendments filed 11/5/04 and the response filed 5/12/04. Claims 1-49 and 62-73 are pending. Claims 50-61 have been canceled. The IDS filed 8/24/2001 has been entered and considered by the Examiner.

Applicant's response to the Requirement for Information under 37 C.F.R 1.105 is hereby acknowledged.

Claim Objections

2. Claim 19 is objected to because of the following informalities: The second recitation of the phrase "said pharmaceutical seller" is not necessary in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 69 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a claim covering every conceivable means for achieving the recited purpose.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In particular, the claim recites "[a] system for determining whether a buyer qualifies for an "own use discount" comprising: a computer configured to perform an "own use" discount audit to determine whether an order qualifies for an "own use" discount." (A system comprising one component, which performs all functions, i.e. a single means claim.) The current claim does not expressly recite "means for" language, However, in *Fiers v. Revel,* (CAFC) 25 USPQ2d 1601, 1606 (1/19/1993), the CAFC affirmed a rejection under 35 USC 112 of a claim reciting a single element that did not literally use "means-plus-function" language.

Instant claim 69 is drawn to any "computer", regardless of construct, that performs the function recited. This parallels the fact situation in *Fiers* wherein "a DNA" and a result was recited. The CAFC stated in *Fiers* at 1606 "Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived". See also *Ex parte Maizel,* (BdPatApp&Int) 27 USPQ2d 1662, 1665 and *Ex parte Kung,* (BdPatApp&Int) 17 USPQ2d 1545, 1547 (1/30/1989) where the claims at issue were rejected for being analogous to single *means* claims even though "means" was not literally used.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-29, 30-49, and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-29

Claim 1 currently recites the conditional limitation " if said associated report supports said order, making a status determination..." However, the claim fails to define or recite criteria, which must be met in order for the report to support the order. Moreover, the use of the "if" before the last step makes it unclear whether the final always performed. In other words, it is unclear whether the applicant's invention is the application of a discount only when the proper support is provided or whether the invention includes the step of determining whether the proper support has been provided and applying a discount to the appropriate orders.

Claim 4 recites "converting said at least on computer file to a format readable by said computer." It is unclear to the Examiner how this claim is intended to further define claim 3, as the Examiner understands a computer file to be a file that is readable by a computer. If the applicant intends to claim a specific format conversion (specific criteria/formats or file extensions), this language should be clarified in the claim. For the purpose of applying art, the examiner will address this limitation as though a computer file is already in a computer readable format.

As per claims 6 and 8, it is unclear how the content or the determination step is distinct from that recited in claim 1. In particular, claims 6 and 8 both recite that the

"determination step depends upon whether the second associated report supports said order." However, the claims fail to provide information or details on how this determination step is performed or what is required for the "second associated report" to support the order. (i.e. how the second report is distinct from the first report)

Claims 2-29 inherit the deficiencies of claim 1 through dependency, and are also rejected.

Claims 30-32:

Claim 30 currently recites a system comprising a first input, a second input, output and software. It is unclear to the Examiner whether the recited system of claim 30 includes a computer processor. Furthermore, it is unclear whether the software is embodied and executable on a computer readable medium.

It should be noted that data structures not embodied on a computer readable media are considered descriptive material. They are therefore considered non-statutory because they are not capable of causing a functional change in a computer. In particular, as currently drafted, the claim fails to define any structural and functional interrelationships between the software and other elements of a computer/computer processor that permit the software's function to be realized and fail to have/produce a tangible result (See MPEP § 2106)

Claims 31-32 inherit the deficiencies of claim 30 through dependency, and are therefore also rejected.

For the purpose of applying art, the Examiner will interpret the claim as having a memory and computer processor for storing and executing the recited software.

However, the Examiner suggests including claim language to clarify the presence of these structures and to define a structural and functional interrelationship between the software and any elements of a computer/computer processor that would permit the software's function to be realized.

Claims 33-49 inherit the deficiencies of claim 30 through dependency and are also rejected.

Claim 48:

Claim 48 currently recites an "auditing system of claim 28 wherein said software..." However, claim 28 is a method claim, not a system claim and does not recite any software components. As such, the dependency chain of claim 48 is unclear to the Examiner. For the purpose of applying art, the Examiner will interpret claim 48 as being dependent from claim 30.

Claim 49 inherits the deficiencies of claim 48 through dependency, and is therefore also rejected.

Claims 70-72

Claim 70 recites the limitation "said auditing computer" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 71 and 72 inherit the deficiencies of claim 70 through dependency and are also rejected.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 1, 9-37,45-49 and 62-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colella et al (USPN 6,003,006) in view of Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'")

[claim 1] Colella discloses a method for processing orders for pharmaceuticals, said method comprising the steps of:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical; (Figs. 4, 6; col. 5, lines 33-43)
- receiving an associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9)
- comparing said order with said associated report; and (col. 4, lines 17-44)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing

agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 9] Colella discloses the method of claim 1 further comprising the step of entering said order as data into a computer. (col. 5, lines 33-43; Fig. 4, 6)

[claim 10] Colella teaches the method of claim 9 wherein the step of receiving said associated report further comprises receiving said report as at least one computer file (i.e. in computer readable format), and wherein the comparison step is performed by said computer. (col. 4, lines 1-9; 17-44; 48-51)

[claim 11] Colella discloses the method of claim 10 further comprising the step of converting said at least one computer file to a format readable by said computer. (col. 4, lines 1-9; 17-44; 48-51)

[claim 12] Colella teaches the method of claim 9 further comprising the step of entering said associated report as data into said computer, (col. 4, lines 1-9) and

wherein the comparison step is performed by said computer. (col. 4, lines 17-44)

[claim 13] Colella discloses the method of claim 9 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and (col. 4, lines 1-9; 17-44; 48-51; col.7, lines 55-61; col. 8, lines 41-67)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an own use discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation

federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 14] Colella discloses a method further comprising the step of converting said at least one computer file to a format readable by said computer. (col. 4, lines 1-9; 17-44; 48-51)

[claim 15] The method of claim 9 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9; col. 8, lines 41-67)
- entering said second associated report as data into said computer; and (col. 4, lines 1-9)
- comparing said second associated report with said order using a computer; (col. 4, lines 17-44; col. 8, lines 41-67) and
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an own use discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 16] Colella discloses the method of claim 1 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; and (col. 4, lines 1-9; col. 8, lines 41-67)
- comparing said second associated report with said order or with said associated report; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination of whether the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 17] Colella discloses a method of claim 16 further comprising the step of placing said order with a pharmaceutical seller based upon certain criteria (col. 5, lines 33-43; col. 6, line 65-col. 7, line 20;col. 8, lines 59-67), but does not disclose applying an own use discount if said status determination identifies the buyer as qualified for said "own use" discount. Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly receive "own use" pharmaceutical discounts on drug orders. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to verify qualifications for pharmaceutical "own use" discounts and to apply the discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 18] Colella discloses a method further comprising the step of sending either said

first associated report or said second associated report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 19] Colella discloses a method further comprising the step of allowing said pharmaceutical seller to have access to either said first associated report or said second associated report. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 20] Colella discloses a method further comprising the step of placing said order with a pharmaceutical seller based upon certain criteria (col. 5, lines 33-43; col. 6, line 65-col. 7, line 20;col. 8, lines 59-67), but does not disclose applying an own use discount if said status determination identifies the buyer as qualified for said "own use" discount. Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly receive "own use" pharmaceutical discounts on drug orders. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to verify qualifications for pharmaceutical "own use" discounts and to apply the discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 21] Colella discloses the method of claim 20 further comprising the step of

sending said associated report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 22] Colella discloses the method of claim 20 further comprising the step of allowing said pharmaceutical seller to have access to said associated report. (col. 4, lines 1-9; col. 5, lines 33-43)

[claim 23] Colella discloses a method further comprising the steps of generating a status report and sending said status report to said pharmaceutical seller. (col. 4, lines 1-9; col. 5, lines 33-43; col. 7, lines 55-61)

[claim 24] Colella discloses the method of claim 20 wherein said buyer is an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; col. 5, lines 33-43; Figure 1A)

[claim 25] Colella discloses the method of claim 24 further comprising the step of arranging for said pharmaceutical seller to directly ship an appropriate quantity of said type of pharmaceutical directly (col. 5, lines 33-43; col. 8, line 59-67) to one of an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical; or at least one nursing home having at least one patient needing said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; Figure 1A)

[claim 26] Colella discloses the method of claim 1 wherein said buyer includes

an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical (col. 3, line 29-col. 4, line 26; col. 5, lines 33-43; Figure 1A)

[claim 27] Colella discloses the method of claim 1 further comprising the step of generating a status report. (col. 7, lines 55-61)

[claim 28] Colella discloses a method further comprising adjusting the order so that the order is supported by said associated report if said comparison results in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 29] Colella discloses the method of claim 28 wherein the step of adjusting said order comprises calculating a stand by requirement for said buyer. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67).

[claim 30] Colella discloses a pharmaceutical order auditing system, said pharmaceutical order auditing system comprising:

- a first input for receiving pharmaceutical order data, said order data comprising a type of pharmaceutical, a quantity of said type of pharmaceutical, and a buyer requesting said quantity of said type of pharmaceutical; (Figure 1; col. 3, lines 29-67; col. 4, lines 8-26; col. 5, lines 33-43)
- a second input for receiving audit data (i.e. receiving an associated report

summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer (Figure 1B; col. 4, lines 1-9))

- software configured to compare said order data with said audit data (i.e. comparing said order with said associated report; and (col. 4, lines 17-44)
- an output for communicating a status determination to a user. (Figs. 1, 4-6;col. 6, lines 31-34, e.g. screen; interfaces; col. 7, lines 55-61—printer)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 31] Colella discloses a pharmaceutical order auditing system wherein said buyer is an entity comprised of at least one retail pharmacy supplying pharmaceuticals to at

least one nursing home, said at least one nursing home having at least one patient needing said type of pharmaceutical. (col. 3, line 29-col. 4, line 26; col. 5, lines 33-43; Figure 1A)

[claim 32] Colella discloses the pharmaceutical order auditing system of claim 31 wherein said audit is gathered from a medication administration record for each of said patients in the at least one nursing home (Figure 1;col. 4, lines 1-26)

[claim 33] Colella discloses a pharmaceutical order auditing system including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 34] Colella discloses the pharmaceutical order auditing system of claim 33 wherein said additional audit data is gathered from a report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer. (col. 4, lines 1-9; col. 8, lines 41-67 --i.e. a physicians order sheet for each of said patients or medication administration record for each of said patients)

[claim 35] Colella discloses the pharmaceutical order auditing system of claim 31 wherein said audit data comprises a type of pharmaceutical, an amount of said type of pharmaceutical requested by each of said retail pharmacies (col. 4, lines 1-26; col. 4, lines 33-43; col. 6, lines 65-col. 7, lines 20) and each of said nursing homes requesting each of said amounts from each of said retail pharmacies (col. 5, lines 33-56). Colella further discloses a system wherein compare said order data with said audit data (i.e. comparing said order with said associated report; and (col. 4, lines 17-44)

However, Colella does not expressly disclose making a status determination if the buyer qualifies for the "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 36] Colella discloses the pharmaceutical order auditing system of claim 35 including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing

agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 37] Colella discloses a system wherein order data further comprises each of said patients needing said quantity of said type of pharmaceutical, (Figure 6; col. 4, lines 1-26; col. 5, lines 33-43) and wherein said audit data further comprises each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 3-9)

[claim 45] Colella discloses the pharmaceutical order auditing system of claim 31 wherein said output is communicated to said user as a status report. (col. 7, lines 55-61)

[claim 46] Colella discloses the pharmaceutical order auditing system of claim 30 including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step

further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 47] Colella discloses the pharmaceutical order auditing system of claim 30 wherein said software is further configured to allow for a tolerance in making said status determination. (col. 7, lines 55-61; col. 9, lines 9-53—e.g. optional override features in the reporting and review functions)

[claim 48] Colella discloses a system wherein the software may adjust the order so that there is a sufficient match between the adjusted order and the audit data and the

requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 49] Colella discloses the pharmaceutical order auditing system of claim 48 wherein said software is configured to calculate a stand by requirement for said buyer if said order needs adjustment. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67).

[claim 62] Colella discloses a computer-implemented method for processing orders for pharmaceuticals, said method comprising the steps of:

- receiving an order comprising a request from a buyer for a quantity of a type of pharmaceutical; (Figs. 4, 6; col. 5, lines 33-43)
- receiving information summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9)
- comparing said order with said information; and (col. 4, lines 17-44)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74,

par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claims 63-64] Colella discloses the pharmaceutical order auditing method wherein said information comprises at least one of a physicians order sheet or medication administration record. (col. 4, lines 1-9; col. 8, lines 41-67)

[claim 65] Colella discloses a method wherein said buyer comprises at least one retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility. (Figure 1A; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 66] Colella teaches a method wherein said buyer comprises at least entity comprising a plurality of retail pharmacies that supply pharmaceuticals to at least one hospital, nursing home, or long term health care facility. (Figure 1A ; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 67] Colella discloses a method wherein said buyer comprises at least one hospital, nursing home, or long-term health care facility. (col. 3, line 20-col. 4, line 44;

col. 5, lines 33-56)

[claim 68] Colella and Gardner teach the method of claim 63 as explained in the rejection of claim 63. Furthermore, Colella discloses a method further comprising adjusting the order to an appropriate sub quantity if so that the requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with order standards so that the order can go through.

[claim 69] Colella discloses a pharmaceutical order auditing system, said pharmaceutical order auditing system comprising:

- a computer for receiving and processing data related to a pharmaceutical order; (Figure 1; col. 3, lines 29-67; col. 4, lines 8-26; col. 5, lines 33-43); and performing comparisons between orders and related data; (col. 4, lines 17-44)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, line 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 70] Colella discloses a system further comprising:

- a second computer in communication with said auditing computer via a network, said second computer being configured to provide said auditing computer with information that summarizes at least one "own use" pharmaceutical need of at least one patient who is supplied with pharmaceuticals by the buyer, (Figures 1A-1B; col. 3, line 9- col. 4, lines 26) and wherein the auditing computer is further configured to perform an audit by comparing said order with said information (i.e. performing comparisons between orders and related data; Figure 1B; col. 4, lines 17-44))

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, line 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts and to apply a discount accordingly. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 71] Colella teaches a system wherein the information comprises information from a physician order sheet (POS) corresponding to said at least one patient or information from a medication administration record (MAR) corresponding to said at least one patient. (col. 4, lines 1-9; col. 8, lines 41-67)

[claim 72] Colella discloses a system wherein the buyer is at least one retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility, or at least one hospital; at least one nursing home; or at least one long term health care facility. (Figure 1A; col. 3, line 29-col. 4, line 26; col. 5, lines 33-43)

[claim 73] Colella discloses a system wherein the computer is further configured to comprising adjust the order to an appropriate subquantity if so that the requirements in a status determination can be met. (col. 6, line 65-col. 7, line 28; col. 8, lines 59-67—see 112, 2nd rejection). The order amount is reduced/deducted if it is not compliant with

order standards so that the order can go through.

9. Claims 2-8 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colella et al (USPN 6,003,006) and Gardner ("Pharmaceutical Scam: Use Audit to Detect 'Pyramid Cube Scheme'") as applied to claims 1 and 30, and in further view of Spurgeon (5,890,129)

[claim 2] Colella teaches method wherein order data may be transmitted over a network (Colella: col. 5, lines 33-43; Fig. 4, 6), but does not expressly disclose that the network includes the Internet. Spurgeon discloses a method wherein medical data is transmitted over a plurality of networks including the Internet. (Figure 1; col. 5, lines 56-65) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Colella and Gardner in combination to transmit information over the Internet. One would have been motivated to include this feature to facilitate the exchange of clinical and business information among users with within an existing environment of disparate hardware and software systems, as suggested by Spurgeon. (col. 3, lines 1-5)

[claims 3-4] Colella discloses a method wherein the step of receiving said associated report further comprises receiving said report as at least one computer file (i.e. in computer readable format), and wherein the comparison step is performed by said computer (col. 4, lines 1-9; 17-44; 48-51)

[claim 5] Colella teaches a method further comprising the step of entering said associated report as data into said computer (col. 4, lines 1-9) and wherein the comparison step is performed by said computer (col. 4, lines 17-44)

[claim 6] Colella discloses the method of claim 2 further comprising the steps of :

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer, said second associated report being received as at least one computer file; and (col. 4, lines 1-9; 17-44; 48-51; col.7, lines 55-61; col. 8, lines 41-67)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether

or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 7] Colella teaches a method further comprising the step of converting said at least one computer file to a format readable by said computer. (col. 4, lines 1-9; 17-44; 48-51—Information is computer readable and therefore in a format readable by the computer.)

[claim 8] Colella discloses the method of claim 2 further comprising the steps of:

- receiving a second associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer; (col. 4, lines 1-9; col. 8, lines 41-67)
- entering said second associated report as data into said computer; and (col. 4, lines 1-9)
- comparing said second associated report with said order or with said associated report using a computer; and (col. 4, lines 17-44)
- wherein the determination step further depends upon whether said second associated report supports said order. (col.7, lines 55-61; col. 8, lines 41-67)

Colella teaches a method of processing "own use" prescription orders as disclosed above, but does not expressly disclose making a status determination if the buyer qualifies for discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44;

Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 38] Colella and Gardner in combination teach the pharmaceutical order auditing system substantially as recited in claim 35 as explained in the rejection of claim 35. Colella further discloses that the information transmitted in the system may be in one of several formats (col. 4, lines 48-51). However, Colella and Gardner do not expressly disclose a system further comprising a converter configured to convert (audit) data to a common format. Spurgeon discloses a system further comprising a translator/converter which translates/converts data from different sources into a common format (col. 6, line 56-60; col. 7, lines 8-16). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Colella and Gardner in combination to include a converter or translator to convert data to a specific format. As suggested by Spurgeon, one would have been motivated to include this feature to accommodate data from a plurality of sources, while still permitting each data provider

to use the proprietary system of their choice (col. 4, lines 56-64)

[claim 39] Colella discloses a system wherein said audit data further comprises medication administration records for each of said patients in each of said nursing homes. (Figure 1B; col. 4, lines 3-9)

[claim 40] Colella discloses the pharmaceutical order auditing system of claim 38 including a plurality of input devices (e.g. a third input device) for receiving additional audit data. (col. 3, lines 29-67) (e.g. receiving associated report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer--col. 4, lines 1-9; col. 8, lines 41-67) and wherein the determination step further depends upon the additional audit information (i.e. associated report supports said order) (col.7, lines 55-61; col. 8, lines 41-67)

However, Colella does not expressly disclose determining whether if the buyer qualifies for an "own use" discount or not. However, Colella does disclose validation/review steps for verifying the request for pharmaceuticals. (col. 7, 66-col. 8, line 13; col. 8, lines 41-44; Figure 1B—audit)

Gardner discloses a method for detecting fraud and ensuring that purchasing agencies qualify for and properly utilize "own use" pharmaceutical discounts. (pg. 74, par. 4) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify to method/ system of Colella to check or verify whether or not purchased pharmaceuticals qualify for "own use" discounts. As suggested by Gardner, one would have been motivated to include this feature to avoid violation

federal codes/statutes while enjoying legal benefits of cost containment. (page 74, par. 2 and 4)

[claim 41] Colella discloses the pharmaceutical order auditing system of claim 40 wherein said additional audit data is gathered from a report summarizing the "own use" pharmaceutical needs of at least one patient who is supplied with pharmaceuticals by said buyer. (col. 4, lines 1-9; col. 8, lines 41-67 --i.e. a physicians order sheet for each of said patients or medication administration record for each of said patients)

[claim 42] Colella and Gardner in combination teach the pharmaceutical order auditing system substantially as recited in claim 40 as explained in the rejection of claim 40. Colella further discloses that the information transmitted in the system may be in one of several formats (col. 4, lines 48-51). However, Colella and Gardner do not expressly disclose a system further comprising a converter configured to convert (audit) data to a common format. Spurgeon discloses a system further comprising a translator/converter which translates/converts data from different sources into a common format (col. 6, line 56-60; col. 7, lines 8-16). At the time of the applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Colella and Gardner in combination to include a converter or translator to convert data to a specific format. As suggested by Spurgeon, one would have been motivated to include this feature to accommodate data from a plurality of sources, while still permitting each data provider to use the proprietary system of their choice (col. 4, lines 56-64)

[claim 43] Colella discloses the system of claim 40 wherein order data further comprises each of said patients needing said quantity of said type of pharmaceutical, (Figure 6; col. 4, lines 1-26; col. 5, lines 33-43) and wherein said audit data further comprises each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 3-9)

[claim 44] Colella discloses the system of claim 38 wherein order data further comprises each of said patients needing said quantity of said type of pharmaceutical, (Figure 6; col. 4, lines 1-26; col. 5, lines 33-43) and wherein said audit data further comprises each of said patients in each of said nursing homes needing each of said amounts of said type of pharmaceuticals. (Figure 1B; col. 4, lines 3-9)

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Gire ("Hospital Procurement and Illegal Price Discrimination") discloses guidelines and limitations regarding "own use" exemptions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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RP

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